IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	
Plaintiffs,	REDACTED - PUBLIC VERSION
v.	C.A. No. 18-095-GMS
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	[redacted]
Defendants.	

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST COMPLAINT

Defendants Celltrion, Inc. and Celltrion Healthcare Co., Ltd. (collectively, "Celltrion") and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals International GmbH (collectively, "Teva") (the Celltrion and Teva Defendants are collectively referred to as Defendants"), hereby respond to the Complaint of Genentech, Inc. ("Genentech"), City of Hope, and Hoffmann-LA Roche Inc. ("HLR") (collectively, "Plaintiffs") as follows. Defendants deny each and every allegation contained in Plaintiffs' Complaint that is not expressly admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications or speculations that arguably may follow from the admitted facts. Defendants deny that Plaintiffs are entitled to the relief requested in the Complaint or to any other relief.

NATURE OF THE CASE

1. Admitted that breast cancer is a serious disease affecting women in the United States. Admitted that "HER2-positive" breast cancer is an aggressive permutation of the disease that involves overexpression of HER2 proteins and/or amplification of HER2 genes. Defendants otherwise lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

3. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

4. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

5. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

6. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

7. Admitted that Celltrion, Inc. is seeking FDA approval of a biosimilar version of Herceptin® called Herzuma® or CT-P6 ("Herzuma®" or "CT-P6"). Admitted that Celltrion, Inc.'s Abbreviated Biologics License Application ("aBLA") references, among other information, Genentech clinical studies of Herceptin,® as required by statute. Teva Pharmaceuticals USA, Inc. will sell and distribute Herzuma® in the United States. Otherwise denied.

8. Admitted that in 2010, Congress provided a pathway for resolving patent disputes relating to biosimilar products through the BPCIA. Admitted that Celltrion, Inc. provided

Genentech with a notice of commercial marketing pursuant to 42 U.S.C. § 262(l). Plaintiffs' allegations regarding the purported rights and requirements under the BPCIA are legal conclusions to which no responses are required. To the extent responses are required, denied. The remaining allegations of this paragraph are also denied.

9. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, admitted that Plaintiffs' Complaint purports to state claims and/or seek relief under 35 US.C. § 271(e)(2), 42 U.S.C. § 262(*l*)(9), 28 U.S.C. § 2201, and 42 U.S.C. § 262(*l*)(8)(B). Otherwise denied.

PARTIES

10. On information and belief, admitted.

11. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

12. On information and belief, admitted.

13. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them on that basis.

14. On information and belief, admitted.

15. Admitted that Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea, with a place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840, South Korea. Otherwise denied.

16. Admitted.

17. Admitted that Celltrion Healthcare Co., Ltd. is a corporation organized under the laws of the Republic of Korea, with a place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840, Korea. Otherwise denied.

18. Admitted that Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Teva Pharmaceuticals International GmbH entered into an exclusive partnership to commercialize Herzuma® in the United States. Otherwise denied.

19. Admitted that Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a place of business at 1090 Horsham Road, North Wales, PA 19454-1090. Otherwise denied.

20. Admitted that Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and a place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland. Otherwise denied.

21. Admitted.

JURISDICTION AND VENUE

22. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, admitted that Plaintiffs' Complaint purports to state claims such that the Court has subject matter jurisdiction over the action. Otherwise denied.

23. Admitted that Celltrion, Inc. is a corporation organized under the laws of the Republic of Korea. The remainder of this paragraph contains a legal conclusion to which no response is required. To the extent a response is required, for purposes of this case only, Celltrion, Inc. does not contest venue in this judicial district. Otherwise denied.

24. Admitted that Celltrion Healthcare Co., Ltd. is a corporation organized under the laws of the Republic of Korea. The remainder of this paragraph contains a legal conclusion to which no response is required. To the extent a response is required, for purposes of this case only, Celltrion Healthcare Co., Ltd. does not contest venue in this judicial district. Otherwise denied.

25. Admitted the Teva Pharmaceuticals USA, Inc. is incorporated in Delaware. This paragraph contains legal conclusions to which no response is required. To the extent a response

is required, for purposes of this case only, Teva Pharmaceuticals USA does not contest venue in this judicial district. Otherwise denied.

26. Admitted that Teva Pharmaceuticals International GmbH is a Swiss company. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this case only, Teva Pharmaceuticals International GmbH does not contest venue in this judicial district. Otherwise denied.

27. Admitted that Celltrion, Inc. filed aBLA No. 761091 with the FDA seeking approval to market its aBLA product. This paragraph otherwise contains legal conclusions to which no response is required. To the extent a response is required, denied.

28. Admitted that Teva Pharmaceuticals USA, Inc. is a Delaware corporation and that it will market and distribute Herzuma® in the United States upon FDA approval. This paragraph otherwise contains legal conclusions to which no response is required. To the extent a response is required, denied.

29. Admitted that Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Teva Pharmaceuticals International GmbH entered into an exclusive partnership to commercialize Herzuma® in the United States upon FDA approval. This paragraph otherwise contains legal conclusions to which no response is required. To the extent a response is required, denied.

THE PARTIES' EXCHANGES UNDER THE BPCIA

30. Admitted that on July 31, 2017, Celltrion, Inc. announced that the FDA had accepted its aBLA for review. Otherwise denied.

31. Admitted.

32. Admitted that Celltrion Inc. and Genentech exchanged correspondence on August 9, 2017, September 19, 2017, September 25, 2017, and October 9, 2017, among other dates, and that on October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents pursuant to

42 U.S.C. § 262(*l*)(3)(A) ("3(A) List"). That correspondence speaks for itself. To the extent the allegations in this paragraph deviate from or otherwise do not accurately reflect the content of this correspondence, denied. To the extent this paragraph contains legal conclusions, no response is required. To the extent a response is required, denied.

33. Admitted that on November 7, 2017, Celltrion, Inc. provided Genentech with a 3(B) Statement. Otherwise denied.

34. Admitted that on January 5, 2018, Genentech purported to provide its detailed statement concerning infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("3(C) Statement"). Admitted that Genentech's purported 3C Statement only addressed 18 of the patents included in Celltrion, Inc.'s 3(A) List. Admitted that with its 3(C) Statement, Genentech proposed "agreeing that all patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(*l*)(4)(A)." Otherwise denied.

35. Admitted that on [redacted], Celltrion, Inc. wrote to Genentech indicating that it wished to litigate all of the patents on Genentech's 3(A) List. Admitted that on [redacted] Celltrion, Inc. notified Genentech that, pursuant to 42 U.S.C. §262(*l*)(8)(A), Celltrion, Inc. was providing notice that commercial marketing of Herzuma® may begin as early as 180 days from the date of the notice. Admitted that on January 11, 2018, Defendants filed suit against Plaintiffs in the U.S. District Court for the Northern District of California asserting claims for declaratory judgments of non-infringement, invalidity, and/or unenforceability of patents addressed in Celltrion, Inc.'s 3(B) Statement. Otherwise denied.

CELLTRION'S aBLA PRODUCT

36. Admitted that Celltrion, Inc. has issued press releases regarding CT-P6. To the extent paragraph 36 purports to characterize the contents of particular press releases, Defendants state that these releases speak for themselves. Otherwise denied.

37. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants state that the cited statute speaks for itself. To the extent the allegations in this paragraph deviate from or otherwise does not reflect or describe the content of this statue, they are denied.

38. Denied.

GENENTECH'S ASSERTED PATENTS

39. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

40. Denied.

41. Denied.

42. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

The Cabilly Patents

43. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

44. Admitted that what purports to be a copy of U.S. Patent No. 6,331,415 ("'415 Patent") is attached to the Complaint as Exhibit A. Admitted that the face of the '415 Patent lists the title as "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," an issue date of December 18, 2001, and Genentech and City of Hope as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

45. Admitted that what purports to be a copy of U.S. Patent No. 7,923,221 ("'221 Patent") is attached to the Complaint as Exhibit B. Admitted that the face of the '221 Patent lists the title as "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," an issue date of April 12, 2011, and Genentech and City of Hope as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

The '213 Patent

46. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Denied that the inventors named on the '213 patent discovered the recited subject matter. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

47. Admitted that what purports to be a copy of U.S. Patent No. 6,407,213 ("'213 Patent") is attached to the Complaint as Exhibit C. Admitted that the face of the '213 Patent lists the title as "Method for Making Humanized Antibodies," an issue date of June 18, 2002, and is assigned on its face to Genentech. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

The Combination Chemotherapy Patents

48. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Denied that any results of the claimed method are unexpected. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

49. Admitted that what purports to be a copy of U.S. Patent No. 7,846,441 ("'441 Patent") is attached to the Complaint as Exhibit D. Admitted that the face of the '441 Patent lists the title as "Treatment with Anti-ErbB2 Antibodies," an issue date of December 7, 2010, and is assigned on its face to Genentech. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

50. Admitted that the face of U.S. Patent No. 7,892,549 ("'549 Patent) indicates that it is a continuation of the '441 Patent. This paragraph also contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied.

51. Admitted that what purports to be a copy of the '549 patent is attached to the Complaint as Exhibit E. Admitted that the face of the '549 Patent lists the title as "Treatment with Anti-ErbB2 Antibodies," an issue date of February 22, 2011, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

52. Admitted that the face of U.S. Patent No. 8,425,908 ("'908 Patent), the '441 Patent, and the '549 Patent each purport to have a claim of priority to the same provisional application. This paragraph also contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

53. Admitted that what purports to be a copy of the '908 Patent is attached to the Complaint as Exhibit F. Admitted that the face of the '908 Patent lists the title as "Treatment

with Anti-ErbB2 Antibodies," an issue date of April 23, 2013, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

The Method of Administration Patents

54. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

55. Admitted that what purports to be a copy of U.S. Patent No. 6,627,196 ("'196 Patent") is attached to the Complaint as Exhibit G. Admitted that the face of the '196 Patent lists the title as "Dosages for Treatment with Anti-ErbB2 Antibodies," an issue date of September 30, 2003, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

56. Admitted that what purports to be a copy of U.S. Patent No. 7,371,379 ("'379 Patent") is attached to the Complaint as Exhibit H. Admitted that the face of the '379 Patent lists the title as "Dosages for Treatment with Anti ErbB2 Antibodies," an issue date of May 13, 2008, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

The Acidic Variants Patents

57. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied.

Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

58. Admitted that what purports to be a copy of U.S. Patent No. 6,339,142 ("'142 Patent") is attached to the Complaint as Exhibit I. Admitted that the face of the '142 Patent lists the title as "Protein Purification," an issue date of January 15, 2002, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

59. Admitted that what purports to be a copy of U.S. Patent No. 6,417,335 ("'335 Patent") is attached to the Complaint as Exhibit J. Admitted that the face of the '335 Patent lists the title as "Protein Purification," an issue date of July 9, 2002, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

60. Admitted that what purports to be a copy of U.S. Patent No. 6,489,447 ("'447 Patent") is attached to the Complaint as Exhibit K. Admitted that the face of the '447 Patent lists the title as "Protein Purification," an issue date of December 3, 2002, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

61. Admitted that what purports to be a copy of U.S. Patent No. 9,249,218 ("'218 Patent") is attached to the Complaint as Exhibit L. Admitted that the face of the '218 Patent lists the title as "Protein Purification," an issue date of February 2, 2016, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

Combination Therapy with Perjeta

62. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. To the extent a response is required, denied. Denied that the claimed therapies are novel. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

63. Admitted that what purports to be a copy of U.S. Patent No. 7,501,122 ("'122 Patent") is attached to the Complaint as Exhibit M. Admitted that the face of the '122 Patent lists the title as "Treatment with Anti-ErbB2 Antibody Combinations," an issue date of March 10, 2009, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

64. Admitted that what purports to be a copy of U.S. Patent No. 7,449,184 ("'184 Patent") is attached to the Complaint as Exhibit N. Admitted that the face of the '184 Patent lists the title as "Fixed Dosing of HER Antibodies," an issue date of November 11, 2008, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

65. Admitted that what purports to be a copy of U.S. Patent No. 8,691,232 ("'232 Patent") is attached to the Complaint as Exhibit O. Admitted that the face of the '232 Patent lists the title as "Extending Time to Disease Progression or Survival in Cancer Patients," an issue date of April 8, 2014, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

HER2 Diagnostic Patents

66. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Denied that the claimed techniques are novel. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

67. Admitted that what purports to be a copy of U.S. Patent No. 7,993,834 ("'834 Patent") is attached to the Complaint as Exhibit P. Admitted that the face of the '834 Patent lists the title as "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy," an issue date of August 9, 2011, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

68. Admitted that what purports to be a copy of U.S. Patent No. 8,076,066 ("'066 Patent") is attached to the Complaint as Exhibit Q. Admitted that the face of the '066 Patent lists the title as "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," an issue date of December 13, 2011, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

69. Admitted that what purports to be a copy of U.S. Patent No. 8,440,402 ("'402 Patent") is attached to the Complaint as Exhibit R. Admitted that the face of the '402 Patent lists the title as "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," an issue date of May 14, 2013, and Genentech as the

assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

Cell Culture, Purification, and Antibody Manufacturing Patents

70. This paragraph contains allegations regarding the scope of patent claims that are legal conclusions to which no response is required. To the extent a response is required, denied. Denied that the claimed techniques are novel. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

71. Admitted that what purports to be a copy of U.S. Patent No. 6,620,918 ("'918 Patent") is attached to the Complaint as Exhibit S. Admitted that the face of the '918 Patent lists the title as "Separation of Polypeptide Monomers," an issue date of September 16, 2003, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

72. Admitted that what purports to be a copy of U.S. Patent No. 7,485,704 ("'704 Patent") is attached to the Complaint as Exhibit T. Admitted that the face of the '704 Patent lists the title as "Reducing Protein A Leaching During Protein A Affinity Chromatography," an issue date of February 3, 2009, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them.

73. Admitted that what purports to be a copy of U.S. Patent No. 7,807,799 ("'799 Patent") is attached to the Complaint as Exhibit U. Admitted that the face of the '799 Patent lists the title as "Reducing Protein A Leaching During Protein A Affinity Chromatography," an issue date of October 5, 2010, and Genentech as the assignee. Defendants lack knowledge or

information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

74. Admitted that what purports to be a copy of U.S. Patent No. 9,428,548 ("'548 Patent") is attached to the Complaint as Exhibit V. Admitted that the face of the '548 Patent lists the title as "Enhanced Protein Purification Through a Modified Protein A Elution," an issue date of August 30, 2016, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

75. Admitted that what purports to be a copy of U.S. Patent No. 6,586,206 ("'206 Patent") is attached to the Complaint as Exhibit W. Admitted that the face of the '206 Patent lists the title as "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," an issue date of July 1, 2003, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

76. Admitted that what purports to be a copy of U.S. Patent No. 6,610,516 ("'516 Patent") is attached to the Complaint as Exhibit X. Admitted that the face the '516 Patent lists the title as "Cell Culture Process," an issue date of August 26, 2003, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

77. Admitted that what purports to be a copy of U.S. Patent No. 6,716,602 ("'602 Patent") is attached to the Complaint as Exhibit Y. Admitted that the '602 Patent lists the title as "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," an issue date of April 6, 2004, and Genentech as the assignee. Defendants lack knowledge or information

sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

78. Admitted that what purports to be a copy of U.S. Patent No. 7,390,660 ("'660 Patent") is attached to the Complaint as Exhibit Z. Admitted that the face of the '660 Patent lists the title as "Methods for Growing Mammalian Cells In Vitro," an issue date of June 24, 2008, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

79. Admitted that what purports to be a copy of U.S. Patent No. 8,460,895 ("'895 Patent") is attached to the Complaint as Exhibit AA. Admitted that the face of the '895 Patent lists the title as "Method for Producing Recombinant Proteins with a Constant Content of pCO_2 in the Medium," an issue date of June 11, 2013, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

80. Admitted that what purports to be a copy of U.S. Patent No. 8,512,983 ("'983 Patent") is attached to the Complaint as Exhibit BB. Admitted that the face of the '983 Patent lists the title as "Production of Proteins in Glutamine-Free Cell Culture Media," an issue date of August 20, 2013, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

81. Admitted that what purports to be a copy of U.S. Patent No. 8,574,869 ("'869 Patent") is attached to the Complaint as Exhibit CC. Admitted that the face of the '869 Patent titled "Prevention of Disulfide Bond Reduction During Recombinant Production of

Polypeptides," an issue date of November 5, 2013,8,574,869 and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

82. Admitted that what purports to be a copy of U.S. Patent No. 8,771,988 ("'988 Patent") is attached to the Complaint as Exhibit DD. Admitted that the face of the '988 Patent lists the title as "Protein Expression From Multiple Nucleic Acids," an issue date of July 8, 2014, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

83. Admitted that what purports to be a copy of U.S. Patent No. 9,080,183 ("'183 Patent") is attached to the Complaint as Exhibit EE. Admitted that the face of the '183 Patent lists the title as "Promoter," an issue date of July 14, 2015, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

84. Admitted that what purports to be a copy of U.S. Patent No. 9,428,766 ("'766 Patent") is attached to the Complaint as Exhibit FF. Admitted that the face of the '766 Patent lists the title as "Protein Expression From Multiple Nucleic Acids," an issue date of August 30, 2016, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

85. Admitted that what purports to be a copy of U.S. Patent No. 9,487,809 ("'809 Patent") is attached to the Complaint as Exhibit GG. Admitted that the '809 Patent lists the title as "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the

Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," an issue date of November 8, 2016, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

86. Admitted that what purports to be a copy of U.S. Patent No. 9,714,293 ("'293 Patent") is attached to the Complaint as Exhibit HH. Admitted that the '293 Patent lists the title as "Production of Proteins in Glutamine-Free Cell Culture Media," an issue date of July 25, 2017 and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

87. Admitted that what purports to be a copy of U.S. Patent No. 8,357,301 ("'301 Patent") is attached to the Complaint as Exhibit II. Admitted that the '301 Patent lists the title as "Chromatography Equipment Characterization," an issue date of January 22, 2013, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

88. Admitted that what purports to be a copy of U.S. Patent No 8,633,302 ("'302 Patent") is attached to the Complaint as Exhibit JJ. Admitted that the face of the '302 Patent lists the title as "Variable Tangential Flow Filtration," an issue date of January 21, 2014, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

89. Admitted that what purports to be a copy of U.S. Patent No. 8,822,655 ("'655 Patent") is attached to the Complaint as Exhibit KK. Admitted that the face of the '655 Patent lists the title as "Pre-filtration Adjustment of Buffer Solutes," an issue date of September 2, 2014, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

90. Admitted that what purports to be a copy of U.S. Patent No. 9,047,438 ("'438 Patent") is attached to the Complaint as Exhibit LL. Admitted that the face of the '438 Patent lists the title as "Chromatography Equipment Characterization," an issue date of June 2, 2015, and Genentech and HLR as the assignees. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

91. Admitted that what purports to be a copy of U.S. Patent No. 6,242,177 ("'177 Patent") is attached to the Complaint as Exhibit MM. Admitted that the face of the '177 Patent lists the title as "Methods and Compositions for Secretion of Heterologous Polypeptides," an issue date of June 5, 2001, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

92. Admitted that what purports to be a copy of U.S. Patent No. 6,121,428 ("'428 Patent") is attached to the Complaint as Exhibit NN. Admitted that the face of the '428 Patent lists the title as "Protein Recovery," an issue date of September 19, 2000, and Genentech as the assignee. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore deny them on that basis.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,331,415

93. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-92 as if fully set forth herein.

94. Defendants admit that Genentech included the ’415 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

95. Denied.

96. Denied.

97. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’415 Patent. Otherwise denied.

98. Denied.

99. Denied.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,923,221

100. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-99 as if fully set forth herein.

101. Defendants admit that Genentech included the ’221 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

102. Denied.

103. Denied.

104. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’221 Patent. Otherwise denied.

105. Denied.

106. Denied.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 6,407,213

107. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-106 as if fully set forth herein.

108. Defendants admit that Genentech included the ’213 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

109. Denied.

110. Denied.

111. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’213 Patent. Otherwise denied.

112. Denied.

113. Denied.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 7,846,441

114. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-113 as if fully set forth herein.

115. Defendants admit that Genentech included the ’441 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

116. Denied.

117. Denied.

118. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’441 Patent. Otherwise denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied

123. Denied.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 7,892,549

124. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-123 as if fully set forth herein.

125. Defendants admit that Genentech included the ’549 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

126. Denied.

127. Denied.

128. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’549 patent. Otherwise denied.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 6,627,196

134. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-133 as if fully set forth herein.

135. Defendants admit that Genentech included the '196 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

136. Denied.

137. Denied

138. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '196 patent. Otherwise denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 7,371,379

144. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-143 as if fully set forth herein.

145. Defendants admit that Genentech included the '379 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

146. Denied.

147. Denied.

148. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '379 patent. Otherwise denied.

149. Denied.

150. Denied.

151. Denied.

152. Denied.

153. Denied.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 6,339,142

154. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-153 as if fully set forth herein.

155. Defendants admit that Genentech included the ’142 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

156. Denied.

157. Denied.

158. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’142 patent. Otherwise denied.

159. Denied.

160. Denied.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 6,417,335

161. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-160 as if fully set forth herein.

162. Defendants admit that Genentech included the ’335 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

163. Denied.

164. Denied.

165. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '335 patent. Otherwise denied.

166. Denied.

167. Denied.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 6,489,447

168. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-167 as if fully set forth herein.

169. Defendants admit that Genentech included the '447 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

170. Denied.

171. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

172. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '447 patent. Otherwise denied.

173. Denied.

174. Denied

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 9,249,218

175. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-174 as if fully set forth herein.

176. Defendants admit that Genentech included the ’218 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

177. Denied.

178. Denied.

179. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’218 patent. Otherwise denied.

180. Denied.

181. Denied.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 8,574,869

182. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-181 as if fully set forth herein.

183. Defendants admit that Genentech included the ’869 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

184. Denied.

185. Denied.

186. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’869 patent. Otherwise denied.

187. Denied.

188. Denied.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 6,620,918

189. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-188 as if fully set forth herein.

190. Defendants admit that Genentech included the ’918 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

191. Denied.

192. Denied.

193. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’918 patent. Otherwise denied.

194. Denied.

195. Denied

COUNT XIV
INFRINGEMENT OF U.S. PATENT NO. 7,485,704

196. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-195 as if fully set forth herein.

197. Defendants admit that Genentech included the ’704 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

198. Denied.

199. Denied.

200. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’704 patent. Otherwise denied.

201. Denied.

202. Denied.

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 7,807,799

203. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-202 as if fully set forth herein.

204. Defendants admit that Genentech included the '799 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

205. Denied.

206. Denied.

207. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '799 patent. Otherwise denied.

208. Denied.

209. Denied.

COUNT XVI
INFRINGEMENT OF U.S. PATENT NO. 9,428,548

210. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-209 as if fully set forth herein.

211. Defendants admit that Genentech included the '548 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

212. Denied.

213. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

214. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '548 patent. Otherwise denied.

215. Denied.

216. Denied.

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 8,633,302

217. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-216 as if fully set forth herein.

218. Defendants admit that Genentech included the '302 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

219. Denied.

220. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

221. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '302 patent. Otherwise denied.

222. Denied.

223. Denied.

COUNT XVIII
INFRINGEMENT OF U.S. PATENT NO. 8,691,232

224. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-223 as if fully set forth herein.

225. Defendants admit that Genentech included the '232 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

226. Denied.

227. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

228. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '232 patent. Otherwise denied.

229. Denied.

230. Denied.

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 8,771,988

231. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-230 as if fully set forth herein.

232. Defendants admit that Genentech included the '988 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

233. Denied.

234. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

235. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '988 patent. Otherwise denied.

236. Denied.

237. Denied.

COUNT XX
INFRINGEMENT OF U.S. PATENT NO. 8,822,655

238. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-237 as if fully set forth herein.

239. Defendants admit that Genentech included the ’655 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

240. Denied.

241. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

242. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’655 patent. Otherwise denied.

243. Denied.

244. Denied.

COUNT XXI
INFRINGEMENT OF U.S. PATENT NO. 9,047,438

245. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-244 as if fully set forth herein.

246. Defendants admit that Genentech included the ’438 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

247. Denied.

248. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

249. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’438 patent. Otherwise denied.

250. Denied.

251. Denied.

COUNT XXII
INFRINGEMENT OF U.S. PATENT NO. 9,080,183

252. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-251 as if fully set forth herein.

253. Defendants admit that Genentech included the '183 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

254. Denied.

255. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

256. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '183 patent. Otherwise denied.

257. Denied.

258. Denied.

COUNT XXIII
INFRINGEMENT OF U.S. PATENT NO. 9,428,766

259. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-258 as if fully set forth herein.

260. Defendants admit that Genentech included the '766 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

261. Denied.

262. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

263. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '766 patent. Otherwise denied.

264. Denied.

265. Denied.

COUNT XXIV
INFRINGEMENT OF U.S. PATENT NO. 9,487,809

266. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-265 as if fully set forth herein.

267. Defendants admit that Genentech included the '809 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

268. Denied.

269. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

270. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '809 patent. Otherwise denied.

271. Denied.

272. Denied.

COUNT XXV
INFRINGEMENT OF U.S. PATENT NO. 9,714,293

273. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-272 as if fully set forth herein.

274. Defendants admit that Genentech included the '293 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

275. Denied.

276. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

277. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '293 patent. Otherwise denied.

278. Denied.

279. Denied.

COUNT XXVI
INFRINGEMENT OF U.S. PATENT NO. 7,449,184

280. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-279 as if fully set forth herein.

281. Defendants admit that Genentech included the '184 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

282. Denied.

283. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

284. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '184 patent. Otherwise denied.

285. Denied.

286. Denied.

COUNT XXVII
INFRINGEMENT OF U.S. PATENT NO. 7,501,122

287. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-286 as if fully set forth herein.

288. Defendants admit that Genentech included the '122 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

289. Denied.

290. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

291. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '122 patent. Otherwise denied.

292. Denied.

293. Denied.

COUNT XXVIII
INFRINGEMENT OF U.S. PATENT NO. 7,993,834

294. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-293 as if fully set forth herein.

295. Defendants admit that Genentech included the '834 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

296. Denied.

297. Denied.

298. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '834 patent. Otherwise denied.

299. Denied.

300. Denied.

COUNT XXIX
INFRINGEMENT OF U.S. PATENT NO. 8,076,066

301. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-300 as if fully set forth herein.

302. Defendants admit that Genentech included the ’066 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

303. Denied.

304. Denied.

305. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’066 patent. Otherwise denied.

306. Denied.

307. Denied.

COUNT XXX
INFRINGEMENT OF U.S. PATENT NO. 8,357,301

308. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-307 as if fully set forth herein.

309. Defendants admit that Genentech included the ’301 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

310. Denied.

311. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

312. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of the ’301 patent. Otherwise denied.

313. Denied.

314. Denied.

COUNT XXXI
INFRINGEMENT OF U.S. PATENT NO. 8,425,908

315. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-314 as if fully set forth herein.

316. Defendants admit that Genentech included the '908 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

317. Denied.

318. Denied.

319. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '908 patent. Otherwise denied.

320. Denied.

321. Denied.

COUNT XXXII
INFRINGEMENT OF U.S. PATENT NO. 8,440,402

322. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-321 as if fully set forth herein.

323. Defendants admit that Genentech included the '402 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

324. Denied.

325. Denied.

326. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '402 patent. Otherwise denied.

327. Denied.

328. Denied.

COUNT XXXIII
INFRINGEMENT OF U.S. PATENT NO. 8,460,895

329. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-328 as if fully set forth herein.

330. Defendants admit that Genentech included the '895 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

331. Denied.

332. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

333. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of the '895 patent. Otherwise denied.

334. Denied.

335. Denied.

COUNT XXXIV
INFRINGEMENT OF U.S. PATENT NO. 8,512,983

336. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-335 as if fully set forth herein.

337. Defendants admit that Genentech included the '983 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

338. Denied.

339. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

340. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 8,512,983. Otherwise denied.

341. Denied.

342. Denied.

COUNT XXXV
INFRINGEMENT OF U.S. PATENT NO. 6,586,206

343. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-342 as if fully set forth herein.

344. Defendants admit that Genentech included the '206 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

345. Denied.

346. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

347. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 6,586,206. Otherwise denied.

348. Denied.

349. Denied.

COUNT XXXVI
INFRINGEMENT OF U.S. PATENT NO. 6,610,516

350. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-349 as if fully set forth herein.

351. Defendants admit that Genentech included the ’516 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

352. Denied.

353. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

354. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 6,610,516. Otherwise denied.

355. Denied.

356. Denied.

COUNT XXXVII
INFRINGEMENT OF U.S. PATENT NO. 6,716,602

357. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-356 as if fully set forth herein.

358. Defendants admit that Genentech included the ’602 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

359. Denied.

360. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

361. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 6,716,602. Otherwise denied.

362. Denied.

363. Denied.

COUNT XXXVIII
INFRINGEMENT OF U.S. PATENT NO. 7,390,660

364. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-363 as if fully set forth herein.

365. Defendants admit that Genentech included the ’660 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

366. Denied.

367. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

368. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 7,390,660. Otherwise denied.

369. Denied.

370. Denied.

COUNT XXXIX
INFRINGEMENT OF U.S. PATENT NO. 6,242,177

371. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-370 as if fully set forth herein.

372. Defendants admit that Genentech included the ’177 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

373. Denied.

374. Denied.

375. Admitted that, by virtue of its inclusion on Genentech’s 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 6,242,177. Otherwise denied.

376. Denied.

377. Denied.

COUNT XL
INFRINGEMENT OF U.S. PATENT NO. 6,121,428

378. Defendants repeat and incorporate here by reference their responses to preceding paragraphs 1-377 as if fully set forth herein.

379. Defendants admit that Genentech included the '428 patent in its 3(A) List. Defendants admit that Celltrion, Inc. provided Genentech with notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Otherwise denied.

380. Denied.

381. Denied.

382. Admitted that, by virtue of its inclusion on Genentech's 3(A) List and in the Complaint, Defendants know of U.S. Patent No. 6,121,428. Otherwise denied.

383. Denied.

384. Denied.

RESPONSE TO PRAYER FOR RELIEF

The remainder of the Complaint recites a prayer for relief for which no response is required. To the extent any response is required, Defendants deny that Genentech is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the Complaint, Defendants rely upon the following defenses:

FIRST DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

One or more claim of the asserted patents are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or any judicially-created doctrine of invalidity including obviousness-type double patenting.

THIRD DEFENSE

The manufacture, use, offer for sale, sale and/or importation into the United States of product described in aBLA No. 761091 has not infringed, does not infringe, and will not infringe one or more valid and enforceable claims of the asserted patents directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

FOURTH DEFENSE

The filing of aBLA No. 761091 has not infringed, does not infringe, and will not infringe one or more valid and enforceable claims of the asserted patents directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

FIFTH DEFENSE

Plaintiffs are not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction, that enjoins any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of the product of aBLA No. 761091.

SIXTH DEFENSE

Defendants' activities reasonably related to the development and submission of information to the FDA fall within the safe harbor provisions of 35 U.S.C. § 271(e)(1).

SEVENTH DEFENSE

One or more claims of the asserted patents are unenforceable due to equitable estoppel, unclean hands, and/or inequitable conduct.

EIGHTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

RESERVATION OF DEFENSES

Defendants reserve their right to assert any additional defenses or counterclaims, at law or equity, which may exist.

COUNTERCLAIMS

Without admitting any of the Plaintiffs' allegations other than those expressly admitted herein, and without prejudice of the rights of Defendants to plead additional Counterclaims as the facts of the matter warrant, Defendants Celltrion, Inc.; Celltrion Healthcare Co., Ltd.; Teva Pharmaceuticals USA, Inc.; and Teva Pharmaceuticals International GmbH (collectively "Counterclaim Plaintiffs") hereby assert the following Counterclaims against Genentech, Inc. ("Genentech"); City of Hope; and Hoffmann-LA Roche Inc. ("HLR") (collectively, "Counterclaim Defendants").

THE PARTIES

1. Celltrion, Inc. is a corporation organized and existing under the laws of the Republic of Korea, with a place of business at 23, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, South Korea.

2. Celltrion Healthcare Co., Ltd. is a corporation organized under the laws of the Republic of Korea, having its place of business at 23, Academy-ro 51, Yeonsu-gu, Incheon, 406-840, South Korea.

3. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a place of business at 1090 Horsham Road, North Wales, PA 19454-1090.

4. Teva Pharmaceuticals International GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and a place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

5. On information and belief, Counterclaim-Defendant Genentech, Inc. is a Delaware corporation with its principal place of business at 1 DNA Way, South San Francisco, CA 94080.

6. On information and belief, Counterclaim-Defendant City of Hope is a not-for-profit organization organized and existing under the laws of California, having its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

7. On information and belief, Counterclaim-Defendant Hoffmann-LA Roche Inc. is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

8. These counterclaims seek declaratory relief arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. The Court has personal jurisdiction over Genentech because, *inter alia*, Genentech subjected itself to the jurisdiction of this Court by filing this action, and because, on information and belief, Genentech researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

10. The Court has personal jurisdiction over City of Hope because, *inter alia*, City of Hope subjected itself to the jurisdiction of this Court by filing this action.

11. The Court has personal jurisdiction over HLR because, *inter alia*, HLR subjected itself to the jurisdiction of this Court by filing this action, and because, upon information and belief, HLR researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in Delaware and

because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

12. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400 and by virtue of the Counterclaim Defendants' filing of this action in this Court.

FACTUAL BACKGROUND

13. According to the United States Food & Drug Administration ("FDA") publication entitled *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations* (the "Purple Book"), Genentech's Biologics License Application ("BLA") No. 103792 for Herceptin® was first approved on September 25, 1998.

14. The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") describes a process whereby the reference product sponsor ("RPS") and a biosimilar applicant may exchange information in advance of an action for patent infringement. As part of this exchange, the BPCIA states that the RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). The BPCIA also states that the biosimilar applicant shall provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I).

15. On May 30, 2017, Celltrion, Inc. submitted its abbreviated Biologics License Application BLA for Herzuma® ("Celltrion's Herzuma® BLA") pursuant to 42 U.S.C. § 262(k). Celltrion Inc.'s aBLA was filed after the expiration of the 4- year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion received notification from the FDA that its aBLA had been accepted for review on July 28, 2017.

16. On August 1, 2017, prior to the deadline under 42 U.S.C. § 262(*l*)(2)(A) for Celltrion, Inc. to produce its aBLA, Genentech wrote a letter to Celltrion, Inc. requesting that Celltrion, Inc. produce vaguely defined categories of information relating to the processes used in the production of Herzuma® "irrespective of whether it is contained in the aBLA," but did not list any patents to which the information sought might be relevant.

17. On August 11, 2017, Celltrion, Inc. timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A), including the aBLA for Herzuma® and other detailed information regarding the manufacturing processes used to make Herzuma®. Specifically, Celltrion, Inc. produced its aBLA, and upstream and downstream manufacturing reports describing in detail the manufacturing process for Herzuma®. Celltrion, Inc.'s production of more than 280,000 pages of technical details and batch records described, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) raw materials used during the manufacture of Herzuma®.

18. Celltrion Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which complied with 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

19. On October 10, 2017, Genentech provided Celltrion, Inc. with its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("the 3(A) List") that Genentech "believe[d] could reasonably be asserted against Celltrion, Inc.'s proposed CT-P6 product based upon a review of the product's aBLA filing." Genentech's 3(A) List included a total of 40 patents, including all of the following 38 patents (collectively, the "Counterclaim Patents"):

i. U.S. Patent No. 6,331,415 ("the '415 patent");

ii. U.S. Patent No. 6,339,142 ("the '142 patent");

iii. U.S. Patent No. 6,407,213 ("the '213 patent");

iv. U.S. Patent No. 6,417,335 ("the '335 patent");

v. U.S. Patent No. 6,489,447 ("the '447 patent");

vi. U.S. Patent No. 6,586,206 ("the '206 patent");

vii. U.S. Patent No. 6,610,516 ("the '516 patent");

viii. U.S. Patent No. 6,620,918 ("the '918 patent");

ix. U.S. Patent No. 6,627,196 ("the '196 patent");

x. U.S. Patent No. 6,716,602 ("the '602 patent");

xi. U.S. Patent No. 7,371,379 ("the '379 patent");

xii. U.S. Patent No. 7,390,660 ("the '660 patent");

xiii. U.S. Patent No. 7,449,184 ("the '184 patent");

xiv. U.S. Patent No. 7,485,704 ("the '704 patent");

xv. U.S. Patent No. 7,501,122 ("the '122 patent");

xvi. U.S. Patent No. 7,807,799 ("the '799 patent");

xvii. U.S. Patent No. 7,846,441 ("the '441 patent");

xviii. U.S. Patent No. 7,892,549 ("the '549 patent");

xix. U.S. Patent No. 7,923,221 ("the '221 patent");

xx. U.S. Patent No. 7,993,834 ("the '834 patent");

xxi. U.S. Patent No. 8,076,066 ("the '066 patent");

xxii. U.S. Patent No. 8,357,301 ("the '301 patent");

xxiii. U.S. Patent No. 8,425,908 ("the '908 patent");

xxiv. U.S. Patent No. 8,440,402 ("the '402 patent");

xxv. U.S. Patent No. 8,460,895 ("the '895 patent");

xxvi. U.S. Patent No. 8,512,983 ("the '983 patent");

xxvii. U.S. Patent No. 8,574,869 ("the '869 patent");

xxviii. U.S. Patent No. 8,633,302 ("the '302 patent");

xxix. U.S. Patent No. 8,691,232 ("the '232 patent");

xxx. U.S. Patent No. 8,771,988 ("the '988 patent");

xxxi. U.S. Patent No. 8,822,655 ("the '655 patent");

xxxii. U.S. Patent No. 9,047,438 ("the '438 patent");

xxxiii. U.S. Patent No. 9,080,183 ("the '183 patent");

xxxiv. U.S. Patent No. 9,249,218 ("the '218 patent");

xxxv. U.S. Patent No. 9,428,548 ("the '548 patent");

xxxvi. U.S. Patent No. 9,428,766 ("the '766 patent");

xxxvii. U.S. Patent No. 9,487,809 ("the '809 patent"); and

xxxviii. U.S. Patent No. 9,714,293 ("the '293 patent").

20. Upon information and belief, U.S. Patent No. 6,331,415, titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells For Use Therein," issued on December 18, 2001, and is assigned to Genentech, Inc. and City of Hope.

21. Upon information and belief, U.S. Patent No. 6,339,142, titled "Protein Purification" issued on January 15, 2002, and is assigned to Genentech, Inc.

22. Upon information and belief, U.S. Patent No. 6,407,213, titled "Method for Making Humanized Antibodies," issued on June 18, 2002, and is assigned to Genentech, Inc.

23. Upon information and belief, U.S. Patent No. 6,417,335, titled "Protein Purification," issued on July 9, 2002, and is assigned to Genentech, Inc.

24. Upon information and belief, U.S. Patent No. 6,489,447, titled "Protein Purification," issued on December 3, 2002, and is assigned to Genentech, Inc.

25. Upon information and belief, U.S. Patent No. 6,586,206, titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," issued on July 1, 2003, and is assigned to Genentech, Inc.

26. Upon information and belief, U.S. Patent No. 6,610,516, titled "Cell Culture Process," issued on August 26, 2003, and is assigned to Genentech, Inc.

27. Upon information and belief, U.S. Patent No. 6,620,918, titled "Separation of Polypeptide Monomers," issued on September 16, 2003, and is assigned to Genentech, Inc.

28. Upon information and belief, U.S. Patent No. 6,627,196, titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on September 30, 2003, and is assigned to Genentech, Inc.

29. Upon information and belief, U.S. Patent No. 6,716,602, titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," issued on April 6, 2004, and is assigned to Genentech, Inc.

30. Upon information and belief, U.S. Patent No. 7,371,379, titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on May 13, 2008, and is assigned to Genentech, Inc.

31. Upon information and belief, U.S. Patent No. 7,390,660, titled "Methods for Growing Mammalian Cells In Vitro," issued on June 24, 2008. Upon information and belief, the '660 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee.

32. Upon information and belief, U.S. Patent No. 7,449,184, titled "Fixed Dosing of HER Antibodies," issued on November 11, 2008, and is assigned to Genentech, Inc.

33. Upon information and belief, U.S. Patent No. 7,485,704, titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on February 3, 2009, and is assigned to Genentech, Inc.

34. Upon information and belief, U.S. Patent No. 7,501,122, titled "Treatment With Anti-ErbB2 Antibody Combinations," issued on March 10, 2009, and is assigned to Genentech, Inc.

35. Upon information and belief, U.S. Patent No. 7,807,799, titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on October 5, 2010, and is assigned to Genentech, Inc.

36. Upon information and belief, U.S. Patent No. 7,846,441, titled "Treatment with Anti-ErbB2 Antibodies," issued on December 7, 2010, and is assigned to Genentech, Inc.

37. Upon information and belief, U.S. Patent No. 7,892,549, titled "Treatment with Anti-ErbB2 Antibodies," issued on February 22, 2011, and is assigned to Genentech, Inc.

38. Upon information and belief, U.S. Patent No. 7,923,221, titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011, and is assigned to Genentech, Inc. and City of Hope.

39. Upon information and belief, U.S. Patent No. 7,993,834, titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the effectiveness of ErbB2 AntiBody Breast Cancer Therapy," issued on August 9, 2011, and is assigned to Genentech, Inc.

40. Upon information and belief, U.S. Patent No. 8,076,066, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on December 13, 2011, and is assigned to Genentech Inc.

41. Upon information and belief, U.S. Patent No. 8,357,301, titled "Chromatography Equipment Characterization," issued on January 22, 2013. Upon information and belief, the '301 patent is assigned to HLR. Upon information and belief, one or more of the Counterclaim-Defendants has the entire right, interest, and title to enforce the '301 patent.

42. Upon information and belief, U.S. Patent No. 8,425,908, titled "Treatment with Anti-ErbB2 Antibodies," issued on April 23, 2013, and is assigned to Genentech, Inc.

43. Upon information and belief, U.S. Patent No. 8,440,402, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on May 14, 2013, and is assigned to Genentech, Inc.

44. Upon information and belief, U.S. Patent No. 8,460,895, titled "Method for Producing Recombinant Proteins with a Constant Content of pCO2 in the Medium," issued on June 11, 2013. Upon information and belief, the '895 patent is assigned to HLR, and Genentech is the exclusive licensee with the sole right to enforce the '895 patent.

45. Upon information and belief, U.S. Patent No. 8,512,983, titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on August 20, 2013. Upon information and belief, Genentech is the owner of all right, title and interest in the '983 patent.

46. Upon information and belief, U.S. Patent No. 8,574,869, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," issued on November 5, 2013, and is assigned to Genentech, Inc.

47. Upon information and belief, U.S. Patent No. 8,633,302, titled "Variable Tangential Flow Filtration," issued on January 21, 2014. Upon information and belief, the '302 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee.

48. Upon information and belief, U.S. Patent No. 8,691,232, titled "Extending Time to Disease Progression or Survival in Cancer Patients," issued on April 8, 2014, and is assigned to Genentech, Inc.

49. Upon information and belief, U.S. Patent No. 8,771,988, titled "Protein expression from multiple nucleic acids," issued on June 24, 2008. Upon information and belief, the '988 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee.

50. Upon information and belief, U.S. Patent No. 8,822,655, titled "Pre-filtration adjustment of buffer solutes," issued on September 2, 2014. Upon information and belief, the '655 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee.

51. Upon information and belief, U.S. Patent No. 9,047,438, titled "Chromatography Equipment Characterization," issued on June 2, 2015, and is assigned to HLR.

52. Upon information and belief, U.S. Patent No. 9,080,183, titled "Promoter," issued on July 14, 2015, and is assigned to HLR.

53. Upon information and belief, U.S. Patent No. 9,249,218, titled "Protein Purification," issued on February 2, 2016, and is assigned to Genentech, Inc.

54. Upon information and belief, U.S. Patent No. 9,428,548, titled "Enhanced Protein Purification through a Modified Protein A Elution," issued on August 30, 2016, and is assigned to Genentech, Inc.

55. Upon information and belief, U.S. Patent No. 9,428,766, titled "Protein expression from multiple nucleic acids," issued on August 30, 2016. Upon information and belief, the '766 patent is assigned to HLR and Genentech, Inc. is the exclusive licensee.

56. Upon information and belief, U.S. Patent No. 9,487,809, titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," issued on November 8, 2016, and is assigned to Genentech, Inc.

57. Upon information and belief, U.S. Patent No. 9,714,293, titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on July 25, 2017, and is assigned to Genentech Inc.

58. 42 U.S.C. § 262(*l*)(3)(A) requires an RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by [the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying each of the Counterclaim Patents on its 3(A) List, Genentech has represented that Genentech has the right to assert the each of the Counterclaim Patents as the patent owner, or exclusive licensee.

59. On November 7, 2017, Celltrion, Inc. timely responded to Genentech's 3(A) List by providing Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I)

(Celltrion, Inc.'s "3(B) Statement"), a 533-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion, Inc.'s opinion that patents included on Genentech's 3(A) List are not infringed and/or are invalid or unenforceable (the "3(B) Statement"). Celltrion, Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion had produced to Genentech.

60. Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion, Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the confidential documents of a third party that were potentially relevant to the CT-P6 manufacturing process. Celltrion, Inc. produced these documents along with recent FDA correspondence related to Celltrion, Inc.'s aBLA at the same time that Celltrion, Inc. served the 3(B) Statement on Genentech. Celltrion, Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

61. Celltrion, Inc.'s 3(B) Statement cited extensively to documents that Celltrion, Inc. had produced to Genentech. Contrary to any allegation by Genentech that Celltrion, Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B) were deficient, Celltrion, Inc. produced substantially more documentation than was required by the statute, such that Genentech had in its possession all the information it needed to determine whether Celltrion's Herzuma® product would infringe Genentech's 3(A) List patents. Regarding each patent included on Genentech's 3(A) List, Celltrion, Inc.'s 3(B) Statement contained [redacted] detailed statements regarding non-infringement, unenforceability, and/or invalidity [redacted] Therefore, Celltrion, Inc.'s 3(B) Statement complied with the requirements of § 262(*l*)(3)(B).

62. On January 5, 2018, Celltrion, Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "3(C) Statement") purporting to describe the basis for Genentech's opinion that some of the patents included on Genentech's 3(A) List are infringed and/or are valid and enforceable. In its 3(C) Statement, Genentech did not provide allegations regarding the validity or infringement of 20 of the patents from its 3(A) List, but reserved the right to assert infringement of these patents in the future.

63. In a letter accompanying Genentech's 3(C) statement, Genentech proposed "agreeing that all patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(*l*)(4)(A)."

64. On January 11, 2018, Celltrion, Inc. wrote to Genentech in response to its 3(C) Statement. Celltrion, Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion, Inc. wished to litigate all of the patents on Genentech's 3(A) List.

65. [redacted]

66. On January 12, 2018, Counterclaim-Defendants filed their Complaint, which alleges infringement of each of the Counterclaim Patents.

67. A justiciable controversy exists as to the infringement and validity of each of the Counterclaim Patents because Counterclaim-Defendants brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of Celltrion's Herzuma® BLA would infringe each of the Counterclaim Patents, and Counterclaim-Plaintiffs have denied the alleged infringement and/or allege that the claims of each of the Counterclaim Patents are invalid and/or unenforceable. A justiciable case or controversy as to

the infringement and validity of each of the Counterclaim Patents furthermore exists because: (i) Genentech included these patents on its 3(A) List of patents regarding which it "believes a claim of patent infringement could reasonably be asserted" based on Celltrion's Herzuma® BLA, (ii) Celltrion, Inc. provided detailed descriptions of its opinion that each of the Counterclaim Patents are not infringed, and/or are invalid or unenforceable in Celltrion's 3(B) Statement, and (iii) as to each of the Counterclaim Patents, Genentech in its 3(C) Statement either explicitly reserved the right to assert infringement in the future or purported to provide the basis for its opinion that the Counterclaim Patents are infringed, valid, and enforceable. This controversy is of sufficient immediacy and reality to warrant the issuance of declaratory judgments, as set forth in each Count below.

COUNT I
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

68. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-67 above as if fully set forth herein.

69. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

70. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(a) because [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

71. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '415 patent include: [redacted]

72. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '415 patent.

73. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

74. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT II
Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

75. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-74 above as if fully set forth herein.

76. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '415 patent are invalid.

77. Non-limiting examples of how one or more claims of the '415 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobulins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

78. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

79. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

80. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '415 patent are invalid.

COUNT III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,339,142

81. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-80 above as if fully set forth herein.

82. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

83. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '142 patent include: [redacted]

84. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '142 patent.

85. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

86. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '142 patent.

COUNT IV
Declaratory Judgment of Invalidity of U.S. Patent No. 6,339,142

87. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-86 above as if fully set forth herein.

88. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '142 patent are invalid.

89. Non-limiting examples of how one or more claims of the '142 patent are invalid include: (1) anticipation by prior art which expressly discloses a composition of trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to less than about 25%.

90. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '142 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

91. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

92. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '142 patent are invalid.

COUNT V
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213

93. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-92 above as if fully set forth herein.

94. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

95. Counterclaim-Plaintiffs will not infringe one or more valid claims of the '213 patent at least because the CT-P6 product [redacted].

96. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '213 patent.

97. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

98. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '213 patent.

COUNT VI
Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

99. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-98 above as if fully set forth herein.

100. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '213 patent are invalid.

101. Non-limiting examples of how one or more claims of the '213 patent are invalid include: 1) anticipation by prior art references teaching substitutions using the Kabat numbering system at sites recited in the '213 patent claims; 2) anticipation by prior art references teaching the structural components recited in the '213 patent claims; 3) obviousness in view of prior art disclosing detailed roadmaps for substitutions in antibody sequences to humanize non-human monoclonal antibodies; 4) indefiniteness because claim terms such as "consensus human variable domain" and "the most frequently occurring amino acid residues at each location in all human immunoglobulins" can have multiple definitions; 5) lack of adequate written description because "comprising non-human Complementarity Determining Region (CDR) amino acid residues which bind an antigen" would require substantial mapping and binding studies not disclosed in the '213 patent specification; and 6) obviousness-type double patenting over claims of U.S. Patent No. 5,821,337.

102. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '213 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

103. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

104. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’213 patent are invalid.

COUNT VII
Declaratory Judgment of Unenforceability of U.S. Patent No. 6,407,213

105. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-104 above as if fully set forth herein. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that the ’213 patent is unenforceable.

106. During the prosecution of the ’213 patent, Genentech and its patent prosecutor made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office and with knowledge that the misrepresentations were material to patentability.

107. Genentech and its patent prosecutor deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 (“’101 patent”) to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech and its patent prosecutor told the Examiner that the ’101 patent does not use the Kabat numbering system, despite its repeated references to “numbering according to Kabat” and “the Kabat system.”

108. Genentech and its patent prosecutor also made deliberate misrepresentations and omissions regarding Queen et al., A Humanized Antibody that Binds to the Interleukin 2 Receptor, Pro. Nat’l Acad. Sci. 86:10029–33 (1989) (“Queen 1989”), including (i) falsely distinguishing Queen 1989 on the ground that it used “sequential numbering,” as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue (“62L”) disclosed in the prior art. Deceptive intent by

Genentech and its patent prosecutor is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

109. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions selected from a set of specific locations, including positions "62L" and "93H." On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

110. On June 12, 1995, Genentech and its patent prosecutor amended the pending claims and deleted references to amino acid position "62L."

111. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

112. In response to the non-final rejection, Genentech and its patent prosecutor once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

113. On October 7, 1997, in a letter signed by Wendy M. Lee on behalf of Genentech, Genentech and Ms. Lee argued in remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." In another submission by Wendy M. Lee on behalf of Genentech later in the prosecution of the '213 patent, Genentech and Ms. Lee repeated the same argument to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

See Applicant Remarks, dated Apr. 26, 2001, at 7.

114. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

115. Contrary to Genentech's and Ms. Lee's representations to the Patent Office—namely, that the '101 patent does not use the Kabat numbering system—the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." '101 patent at 8:15–18. In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93 in the heavy chain. *See id.* at 15:17–37. Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

116. In order to overcome the § 102 rejection based on the '101 patent, Genentech and its patent prosecutor falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's and its patent prosecutor's false and misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent. But-for Genentech's and its patent prosecutor's misrepresentations, the Patent Office would not have allowed the claims of the '213 patent.

117. Genentech and its patent prosecutor also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential numbering,"

as opposed to the Kabat numbering system. At the Examiner's request, Genentech and its patent prosecutor submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims. See Applicant Remarks at 6–10 (Oct. 7, 2997) ("As requested by the Examiner in the interview, alignments of heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen et al.) with sequential and Kabat residue numbering is attached."). The alignments provided by Genentech and its patent prosecutor to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." See Queen 1989 at 10032. Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."

118. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the '213 patent are enforceable.

119. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

120. Counterclaim-Plaintiffs are entitled to a judicial declaration that the '213 patent is unenforceable.

COUNT VIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

121. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-120 above as if fully set forth herein.

122. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '335 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

123. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(g) because [redacted]

124. An additional non-limiting example of how Counterclaim-Plaintiffs will not infringe any valid claim of the '335 patent is [redacted]

125. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '335 patent.

126. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

127. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’335 patent.

COUNT IX
Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

128. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-127 above as if fully set forth herein.

129. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’335 patent are invalid.

130. One or more claims of the ’335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ’335 patent. Non-limiting examples of how one or more claims of the ’335 patent are invalid include: (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the ’335 patent regarding “purifying” of “an antibody from a composition comprising the antibody and a contaminant” by “loading the composition onto a cation exchange resin” and “eluting the contaminant from the cation exchange resin”; and (2) obviousness in view of prior art disclosing the purification of an antibody by loading that antibody onto a cation exchange resin.

131. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

132. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

133. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’335 patent are invalid.

COUNT X
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447

134. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-133 above as if fully set forth herein.

135. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’447 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

136. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’447 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the ’447 patent under 35 U.S.C. § 271(g) because [redacted]

137. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’447 patent include [redacted]

[redacted]

138. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '447 patent.

139. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

140. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent.

COUNT XI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

141. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-140 above as if fully set forth herein.

142. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

143. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

144. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '206 patent include [redacted]

145. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '206 patent.

146. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

147. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT XII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

148. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-147 above as if fully set forth herein.

149. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

150. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(g) because [redacted]

151. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '516 patent include: [redacted]

152. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '516 patent.

153. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

154. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT XIII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

155. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-154 above as if fully set forth herein.

156. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '516 patent are invalid.

157. Non-limiting examples of how one or more claims of the '516 patent are invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness in view of prior art disclosing producing human glycoproteins with increased abundance of particular glycoforms by including butyrate salts in the media and/or controlling the temperature of the culture in the range of 30° C. to 35° C, and (3) to the extent not obvious, lack of enablement of the claimed "process for producing a human glycoprotein having multiple glycoforms" with "an increased percentage of glycoprotein molecules having one glycoform" because there is no disclosure in the specification of how to perform the claimed process to produce glycoproteins other than t-PA, and undue experimentation would have been required for a POSA to do so.

158. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States

Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

159. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

160. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’516 patent are invalid.

COUNT XIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

161. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-160 above as if fully set forth herein.

162. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’918 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

163. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’918 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the ’918 patent under 35 U.S.C. § 271(g) [redacted]

164. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’918 patent include [redacted]

[redacted]

165. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '918 patent.

166. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

167. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT XV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,627,196

168. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-167 above as if fully set forth herein.

169. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

170. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent include: 1) Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a) because Counterclaim-Plaintiffs will not treat

patients; and (2) Counterclaim-Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(b) or (c) at least because Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

171. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '196 patent.

172. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

173. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT XVI
Declaratory Judgment of Invalidity of U.S. Patent No. 6,627,196

174. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-173 above as if fully set forth herein.

175. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '196 patent are invalid.

176. Non-limiting examples of how one or more claims of the '196 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '196 patent;

and 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement.

177. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '196 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

178. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

179. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '196 patent are invalid.

COUNT XVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602

180. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-179 above as if fully set forth herein.

181. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

182. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

183. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '602 patent include: [redacted]

184. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '602 patent.

185. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

186. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

COUNT XVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602

187. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-186 above as if fully set forth herein.

188. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '602 patent are invalid.

189. Non-limiting examples of how one or more claims of the '602 patent are invalid include: (1) lack of enablement of the claimed "method for increasing product yield of a properly folded polypeptide," to the extent it encompasses production of protein in host cells other than prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the '602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '602 patent.

190. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

191. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

192. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '602 patent are invalid.

COUNT XIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,371,379

193. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-192 above as if fully set forth herein.

194. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '379 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

195. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent include: 1) Counterclaim-Plaintiffs will not infringe one or more claims of the '379 patent under 35 U.S.C. § 271(a) because Counterclaim-Plaintiffs will not treat patients; and (2) Counterclaim-Plaintiffs also will not infringe one or more claims of the '379 patent under 35 U.S.C. §§ 271(b) or (c) at least because Counterclaim-Plaintiffs will not encourage another party to practice the claimed methods because [redacted]

196. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '379 patent.

197. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

198. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '379 patent.

COUNT XX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,371,379

199. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-198 above as if fully set forth herein.

200. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '379 patent are invalid.

201. Non-limiting examples of how one or more claims of the '379 patent are invalid include: 1) obviousness in view of prior art disclosing a motivation to pursue a less frequent dosing regimen, and the safety and efficacy of the claimed dosing regimen of the '379 patent; 2) to the extent Genentech argues that the person of ordinary skill in the art would not have expected that administration of trastuzumab less frequently than the half-life reported in the prior art to be successful without knowledge of its purportedly longer half-life, lack of enablement; and 3) indefiniteness because claim terms such as "the sum of the effective amounts" can have multiple definitions.

202. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '379 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

203. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

204. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '379 patent are invalid.

COUNT XXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660

205. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-204 above as if fully set forth herein.

206. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '660 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

207. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g) because [redacted]

208. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe any valid claim of the '660 patent include [redacted]

209. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '660 patent.

210. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

211. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’660 patent.

COUNT XXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,449,184

212. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-211 above as if fully set forth herein.

213. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’184 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

214. For example, Counterclaim-Plaintiffs will not directly infringe any claim of the ’184 patent because all the claims are all directed to methods of treating patients and Counterclaim-Plaintiffs will not treat patients. Counterclaim-Plaintiffs will also not induce infringement because [redacted].

215. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '184 patent.

216. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

217. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '184 patent.

COUNT XXIII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,449,184

218. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-217 above as if fully set forth herein.

219. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '184 patent are invalid.

220. Non-limiting examples of how one or more claims of '184 patent are invalid is because the claims are invalid under 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious over the prior art, including at least U.S. App. 10/619,754, Canadian Patent Application 2,376,596, WO01000245, and prior art that describes a phase 1b study demonstrating the efficacy of the combination of pertuzumab and capecitabine, the fixed doses of the claims, and disclosing or suggesting the other elements of the claims.

221. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '184 patent are invalid for failure to comply with the requirements of Title 35 of the United States

Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

222. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

223. Counterclaim-Plaintiffs are entitled to a judicial declaration that claims of the '184 patent are invalid.

COUNT XXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704

224. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-223 above as if fully set forth herein.

225. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

226. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(g) because [redacted]

227. An additional, non-limiting example of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '704 patent is [redacted]

[redacted]

228. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’704 patent.

229. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

230. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’704 patent.

COUNT XXV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,501,122

231. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-230 above as if fully set forth herein.

232. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’122 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

233. For example, Counterclaim-Plaintiffs will not directly infringe any claim of the ’122 patent because all the claims are all directed to methods of treating patients and Counterclaim-Plaintiffs will not treat patients. Counterclaim-Plaintiffs will also not induce

infringement because [redacted]

234. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '122 patent.

235. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

236. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 patent.

COUNT XXVI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,501,122

237. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-236 above as if fully set forth herein.

238. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '122 patent are invalid.

239. As one non-limiting example, one or more claims of the '122 patent are invalid under 35 U.S.C. § 103 as obvious over the prior art, including at least the original prescribing information for HERCEPTIN® and prior art disclosing that humanized 2C4 antibody and HERCEPTIN® bind to different ErbB2 epitopes and suggesting their additive therapeutic effect when combined or co-administered.

240. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '122 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

241. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

242. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '122 patent are invalid.

COUNT XXVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

243. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-242 above as if fully set forth herein.

244. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

245. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(g) because [redacted]

246. An additional, non-limiting example of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '799 patent is [redacted]

247. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '799 patent.

248. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

249. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT XXVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

250. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-249 above as if fully set forth herein.

251. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '799 patent are invalid.

252. For example, one or more claims of the '799 patent are invalid as anticipated or obvious in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent, including prior art that disclosed carrying out the claimed methods at room temperature of 18°C to 25°C.

253. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '799 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

254. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

255. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '799 patent are invalid.

COUNT XXIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,846,441

256. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-255 above as if fully set forth herein.

257. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

258. For example, Counterclaim-Plaintiffs will not directly infringe any claim of the '441 patent because all the claims are directed to methods of treating patients, and Counterclaim-Plaintiffs will not treat patients. Counterclaim-Plaintiffs will also not induce infringement because [redacted]

[redacted] In addition, there are substantial noninfringing uses for CT-P6. [redacted]

259. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '441 patent.

260. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

261. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '441 patent.

COUNT XXX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,441

262. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-261 above as if fully set forth herein.

263. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '441 patent are invalid.

264. Non-limiting examples of how one or more claims of the '441 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed combination, and the safety and efficacy of the same; 2) indefiniteness because claim terms such

as "an amount effective to extend the time to disease progression without increase in overall severe adverse events" and "sum of the effective amounts" can have multiple definitions; and 3) lack of written description because, to the extent the claim limitation can be understood, the specification does not demonstrate possession of the claim limitation "without increase in overall severe adverse events."

265. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '441 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

266. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

267. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '441 patent are invalid.

COUNT XXXI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,892,549

268. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-267 above as if fully set forth herein.

269. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '549 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

270. For example, Counterclaim-Plaintiffs will not directly infringe any claim of the '549 patent because all the claims are all directed to methods of treating patients and Counterclaim-Plaintiffs will not treat patients.

271. Counterclaim-Plaintiffs will not induce infringement of the '549 patent claims because, [redacted]

272. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '549 patent.

273. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

274. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’549 patent.

COUNT XXXII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,892,549

275. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-274 above as if fully set forth herein.

276. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’549 patent are invalid.

277. Non-limiting examples of how one or more claims of the ’549 patent are invalid include: 1) obviousness over prior art that establishes a motivation to use the claimed combination, and the safety and efficacy of the same; 2) lack of enablement and written description with respect to the claimed further “growth inhibitory” or “therapeutic” agent; 3) and indefiniteness because claim terms such as “an amount effective to extend the time to disease progression” can have multiple definitions.

278. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’549 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

279. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

280. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’549 patent are invalid.

COUNT XXXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

281. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-280 above as if fully set forth herein.

282. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’221 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

283. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’221 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the ’221 patent under 35 U.S.C. § 271(g) because [redacted]

284. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’221 patent include: [redacted]

285. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’221 patent.

286. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

287. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’221 patent.

COUNT XXXIV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

288. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-287 above as if fully set forth herein.

289. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of ’221 patent are invalid.

290. Non-limiting examples of how one or more claims of the ’221 patent are invalid include: (1) lack of enablement of the claimed “process for producing an immunoglobulin molecule,” to the extent it encompasses both in vivo and in vitro assembly, because there is no disclosure in the specification of how to produce an antibody in vivo in an microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the in vivo assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobulins (with heavy and light chains) in a single host cell using a plasmid containing

genes. In addition, one or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent.

291. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

292. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

293. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '221 patent are invalid.

COUNT XXXV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,993,834

294. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-293 above as if fully set forth herein.

295. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '834 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

296. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '834 patent include: [redacted]

[redacted]

297. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’834 patent.

298. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

299. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’834 patent.

COUNT XXXVI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834

300. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-299 above as if fully set forth herein.

301. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’834 patent are invalid.

302. Non-limiting examples of how one or more claims of the ’834 patent are invalid include: (1) the claims are indefinite because they fail to identify a baseline likelihood of

effectiveness from which the meaning of the claimed method can be ascertained; (2) the claims are invalid for lack of written description because the patent fails to disclose any data or information to support the claimed correlations between test results and treatment; (3) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural correlation between known diagnostic tests and responses rates to a known method of treatment; (4) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; (5) the claims are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

303. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’834 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

304. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

305. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’834 patent are invalid.

COUNT XXXVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,076,066

306. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-305 above as if fully set forth herein.

307. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '066 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

308. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claim of the '066 patent include: [redacted]

309. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '066 patent.

310. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

311. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’066 patent.

COUNT XXXVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,076,066

312. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-311 above as if fully set forth herein.

313. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that the ’066 patent is invalid.

314. Non-limiting examples of how the ’066 patent is invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

315. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the ’066 patent are

invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

316. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

317. Counterclaim-Plaintiffs are entitled to a judicial declaration that all claims of the '066 patent are invalid.

COUNT XXXIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301

318. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-317 above as if fully set forth herein.

319. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '301 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

320. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(g) because [redacted]

321. Additional, non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '301 patent include [redacted]

[redacted]

322. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’301 patent.

323. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

324. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’301 patent.

COUNT XL
Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301

325. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-324 above as if fully set forth herein.

326. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’301 patent are invalid.

327. A non-limiting example of how one or more claims of the ’301 patent are invalid include that the claims of the ’301 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

328. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

329. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

330. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’301 patent are invalid.

COUNT XLI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,425,908

331. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-330 above as if fully set forth herein.

332. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’908 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

333. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’908 patent include: [redacted]

[redacted]

334. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '908 patent.

335. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

336. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '908 patent.

COUNT XLII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908

337. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-336 above as if fully set forth herein.

338. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '908 patent are invalid.

339. Non-limiting examples of how one or more claims of the '908 patent are invalid include because the claims are invalid as obvious in view of the prior art, including at least Tokuda et al., In Vitro and In Vivo Anti-Tumour Effects of a Humanised Monoclonal Antibody Against c-erbB-2 Product, 73 BRITISH J. CANCER 1362-1365 (1996); A. Hendlisz et al.,

Diagnosis and Treatment of Gastric Cancer, 49(5) DRUGS 711-720 (1995) and M. Pegram et al., Phase II Study of Intravenous Recombinant Humanized Anti-p185 HER-2 Monoclonal Antibody (rhuMAB HER-2) Plus Cisplatin in Patients with HER-2/NEU Overexpressing Metastatic Breast Cancer, 14 PROC. AM. SOC'Y CLIN. ONCOLOGY 106, abs. 124.

340. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '908 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

341. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

342. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '908 patent are invalid.

COUNT XLIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,440,402

343. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-342 above as if fully set forth herein.

344. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '402 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

345. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '402 patent include: [redacted]

[redacted]

346. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '402 patent.

347. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

348. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '402 patent.

COUNT XLIV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402

349. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-348 above as if fully set forth herein.

350. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '402 patent are invalid.

351. Non-limiting examples of how one or more claims of the ’402 patent are invalid include: (1) the claims are directed to patent-ineligible subject matter, as they do no more than recite a natural law relating known biomarkers to known disposition to respond to treatment with trastuzumab; (2) the claims are invalid for lack of written description because the patent fails to show a direct correlation between treatment responsiveness and IHC scores of 0/1+; (3) the claims are obvious in view of prior art disclosing methods for treating patients based on her2 gene amplification or HER2 protein expression and known discrepancies and comparative advantages between the various methods; and (4) claims 2-3, 5-6 are anticipated by prior art describing the treatment of patients with trastuzumab and a chemotherapeutic agent based on HER2 protein overexpression by IHC or her2 gene amplification, wherein some of the patients included for treatment based on her2 gene amplification would have been determined to have IHC scores of 0 or 1+ had they been tested using IHC.

352. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’402 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

353. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

354. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’402 patent are invalid.

COUNT XLV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

355. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-354 above as if fully set forth herein.

356. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

357. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(g) because [redacted]

358. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '895 patent include: [redacted]

359. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '895 patent.

360. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

361. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’895 patent.

COUNT XLVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

362. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-361 above as if fully set forth herein.

363. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’983 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

364. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’983 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs will not infringe the product claim of the ’983 patent (claim 25) under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the ’983 patent under 35 U.S.C. § 271(g) because [redacted]

365. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '983 patent include: [redacted]

366. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '983 patent.

367. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

368. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

COUNT XLVII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

369. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-368 above as if fully set forth herein.

370. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '983 patent are invalid.

371. Non-limiting examples of how one or more claims of the ’983 patent are invalid include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM, and art disclosing the production of therapeutic proteins, including anti-CD20 antibodies, in CHO cells.

372. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’983 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

373. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

374. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’983 patent are invalid.

COUNT XLVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

375. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-374 above as if fully set forth herein.

376. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’869 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

377. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(g) because [redacted]

378. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '869 patent include: [redacted]

379. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '869 patent.

380. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

381. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT XLIX
Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

382. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-381 above as if fully set forth herein.

383. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '869 patent are invalid.

384. Non-limiting examples of how one or more claims of the '869 patent are invalid include: (1) lack of written description for the claim term "following fermentation, sparging the pre-harvest or harvested culture fluid" as the patent is silent concerning any air sparging of a pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '869 patent.

385. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

386. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

387. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '869 patent are invalid.

COUNT L
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

388. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-387 above as if fully set forth herein.

389. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

390. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(g) because [redacted]

391. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '302 patent include that [redacted]

392. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '302 patent.

393. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

394. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT LI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,691,232

395. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-394 above as if fully set forth herein.

396. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of '232 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

397. For example, Counterclaim-Plaintiffs will not directly infringe any claim of the '232 patent because all the claims are all directed to methods of treating patients and Counterclaim-Plaintiffs will not treat patients. Counterclaim-Plaintiffs will also not induce infringement because [redacted]

398. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '232 patent.

399. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

400. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '232 patent.

COUNT LII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,691,232

401. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-400 above as if fully set forth herein.

402. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '232 patent are invalid.

403. A non-limiting example of how one or more claims of the '232 patent are invalid is because the claims are invalid under 35 U.S.C. § 102 as anticipated by the prior art, including at least U.S. Application No. 10/619,754.

404. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '232 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

405. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

406. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '232 patent are invalid.

COUNT LIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988

407. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-406 above as if fully set forth herein.

408. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for

Celltrion, Inc.'s opinion that the '988 patent would not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

409. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g) because [redacted]

410. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '988 patent include [redacted]

411. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '988 patent.

412. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

413. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

COUNT LIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655

414. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-413 above as if fully set forth herein.

415. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

416. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(g) because [redacted]

417. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claim of the '655 patent include [redacted].

418. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '655 patent.

419. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

420. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

COUNT LV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655

421. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-420 above as if fully set forth herein.

422. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '655 patent are invalid.

423. Non-limiting examples of how the '655 patent is invalid include a failure to claim patentable subject matter as each claim of the '655 patent is directed towards an abstract idea, including the use of two equations to determine how to adjust a "first concentration" of buffer substance to arrive at "a second concentration" in order to allegedly achieve a more consistent preparation of immunoglobulin after concentration by tangential flow filtration.

424. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '655 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

425. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

426. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the '655 patent are invalid.

COUNT LVI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438

427. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-426 above as if fully set forth herein.

428. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '438 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

429. For example, Counterclaim-Plaintiffs will not infringe any claim of the '438 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [redacted]

430. Additional, non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '438 patent include [redacted]

431. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '438 patent.

432. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

433. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’438 patent.

COUNT LVII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438

434. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-433 above as if fully set forth herein.

435. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’438 patent are invalid.

436. A non-limiting example of how one or more claims of the ’438 patent are invalid include that the claims of the ’438 patent, which recite methods for using a mathematical formula to determine whether a re-usable chromatography column packing has reduced separation efficacy when used at least for the second time in a purification of a polypeptide, are directed essentially to a method of calculating, using a mathematical formula, an inert change of a property of the chromatography material, and thus are invalid as unpatentable subject matter under 35 U.S.C. § 101.

437. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether the claims of the ’438 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

438. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

439. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’438 patent are invalid.

COUNT LVIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183

440. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-439 above as if fully set forth herein.

441. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’183 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

442. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’183 patent under 35 U.S.C. § 271(a) [redacted]. Counterclaim-Plaintiffs also will not infringe one or more claims of the ’183 patent under 35 U.S.C. § 271(g) because [redacted]

443. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’183 patent include [redacted]

444. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '183 patent.

445. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

446. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

COUNT LIX
Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183

447. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-446 above as if fully set forth herein.

448. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '183 patent are invalid.

449. Non-limiting examples of how one or more claims of the '183 patent are invalid include obviousness in view of prior art disclosing the use of truncated versions of the SV40 promotor to drive protein expression and art disclosing the use of weaker promotor sequences to improve protein expression. In addition, one or more claims of the '183 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '183 patent.

450. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the '183 patent are invalid for failure to comply with the requirements of Title 35 of the United States

Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

451. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

452. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’183 patent are invalid.

COUNT LX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,249,218

453. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-452 above as if fully set forth herein.

454. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’218 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

455. Non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’218 patent include: [redacted]

456. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’218 patent.

457. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

458. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’218 patent.

COUNT LXI
Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218

459. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-458 above as if fully set forth herein.

460. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’218 patent are invalid.

461. Non-limiting examples of how one or more claims of the ’218 patent are invalid include: (1) anticipation by prior art which expressly disclosed a therapeutic lyophilized composition comprising trastuzumab and at most about 18% acidic variants thereof and a pharmaceutically acceptable carrier, and inherently disclosed any valid remaining limitations; (2) obviousness in view of prior art disclosing reasons and methods for separating native trastuzumab from deamidated acidic variants, to reduce the amount of deamidated variants in a pharmaceutical composition to low levels, including levels of 13%, for pharmaceutical compositions.

462. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether one or more claims of the ’218 patent are invalid for failure to comply with the requirements of Title 35 of the United States

Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

463. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

464. Counterclaim-Plaintiffs are entitled to a judicial declaration that one or more claims of the ’218 patent are invalid.

COUNT LXII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548

465. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-464 above as if fully set forth herein.

466. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’548 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

467. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the ’548 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the ’548 patent under 35 U.S.C. § 271(g) because [redacted]

468. An additional non-limiting example of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the ’548 patent include [redacted]

[redacted]

469. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the ’548 patent.

470. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

471. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’548 patent.

COUNT LXIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766

472. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-471 above as if fully set forth herein.

473. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.’s opinion that one or more claims of the ’766 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

474. For example, Counterclaim-Plaintiffs will not infringe the sole claim of the ’766 patent under 35 U.S.C. § 271(a) because [redacted]

[redacted]

475. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe the sole claim of the '766 patent include [redacted]

476. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '766 patent.

477. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

478. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '766 patent.

COUNT LXIV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809

479. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-478 above as if fully set forth herein.

480. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

481. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(g) because [redacted]

482. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '809 patent include [redacted]

483. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '809 patent.

484. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

485. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT LXV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293

486. Counterclaim-Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-485 above as if fully set forth herein.

487. On November 7, 2017, Celltrion, Inc. provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion, Inc.'s opinion that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P6.

488. For example, Counterclaim-Plaintiffs will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(a) [redacted] Counterclaim-Plaintiffs also will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(g) because [redacted]

489. Additional non-limiting examples of how Counterclaim-Plaintiffs will not infringe one or more valid claims of the '293 patent include [redacted]

490. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants concerning whether Counterclaim-Plaintiffs will infringe any valid and enforceable claim of the '293 patent.

491. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

492. Counterclaim-Plaintiffs are entitled to a judicial declaration that Counterclaim-Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs respectfully request that this Court enter judgment in their favor against Counterclaim-Defendants and grant the following relief:

a) Declare that Counterclaim-Plaintiffs have not, do not, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,489,447; 6,586,206; 6,610,516; 6,620,918; 6,627,196; 6,716,602; 7,371,379; 7,390,660; 7,449,184; 7,485,704; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,460,895; 8,512,983; 8,574,869; 8,633,302; 8,691,232; 8,771,988; 8,822,655; 9,047,438; 9,080,183; 9,249,218; 9,428,548; 9,428,766; 9,487,809; and 9,714,293.

b) Declare that one or more claims of U.S. Patent Nos. 6,331,415; 6,339,142; 6,407,213; 6,417,335; 6,610,516; 6,627,196; 6,716,602; 7,371,379; 7,449,184; 7,501,122; 7,807,799; 7,846,441; 7,892,549; 7,923,221; 7,993,834; 8,076,066; 8,357,301; 8,425,908; 8,440,402; 8,512,983; 8,574,869; 8,691,232; 8,822,655; 9,047,438; 9,080,183; and 9,249,218 are invalid.

c) Declare that U.S. Patent No. 6,407,213 is unenforceable.

d) Declare that this is an exceptional case in favor of Counterclaim-Plaintiffs and award Counterclaim-Plaintiffs their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

e) Award Counterclaim-Plaintiffs costs and expenses.

f) Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

/s/ Karen E. Keller

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Defendants

OF COUNSEL:
Elaine H. Blais
Daryl L. Wiesen
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Elizabeth J. Holland
Robert V. Cerwinski
Cynthia Lambert Hardman
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018

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